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Hanan Keren

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EXAMINER

MALLARI, PATRICIA C

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/556,483	Applicant(s) KEREN ET AL.	
	Examiner PATRICIA C. MALLARI	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-145 is/are pending in the application.
- 4a) Of the above claim(s) 78,85-87,108 and 117-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 75-77,79-84,88-107 and 109-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/29/09, 2/1/09, 7/24/08, 11/14/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 78, 85-87, 108, and 117-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species B1 (78 and 108) , species A2 (85-87) and group II (117-145), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/16/09.

Applicant's election with traverse of Group I and species A1 and B2 in the reply filed on 6/16/09 is acknowledged. The traversal is on the ground(s) that the examiner has not provided appropriate information indicating a serious search burden. This is not found persuasive because the application is a national stage application, such that unity of invention practice under MPEP Chapter 1800 and not restriction practice under MPEP Chapter 800 is applied to this application (see MPEP 201 and MPEP 1850 for details). The Office action filed 2/18/09 appropriately set forth reasons for lack of unity.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statements filed 5/29/09, 2/1/09, 7/24/08, and 11/14/05 have been considered

Claim Objections

Claims 92, 96, and 105 are objected to because of the following informalities:

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On line 2 of claim 92, "to so as to" should be replaced with "so as to".

On line 5 of claim 96, "being" should be replaced with "are".

On line 4 of claim 105, "comprising" should be replaced with "further comprising".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 75-77, 79-84, 88-107, 109-116 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Each of claims 75 and 105 recites "to substantially increase a signal-to-noise ratio". The metes and bounds of "substantially increase" are unclear, thereby rendering the claim indefinite. Applicants should clarify.

Claim 81 recites "substantially larger". The metes and bounds of "substantially larger" are unclear, thereby rendering the claim indefinite. Applicants should clarify.

Claim 93 recites "substantial constant sensitivity". The metes and bounds of "substantial constant sensitivity" are unclear, thereby rendering the claim indefinite. Applicants should clarify.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 75, 79, 80, 88-96, 101, 102, 105, 109, and 110 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,642,734 to Ruben et al.

Regarding claims 75 and 105, Ruben teaches a system comprising a radiofrequency generator 34 for generating output radiofrequency signals (col. 5, lines 20-30 of Ruben). A plurality of electrodes 48A, B 50A, B are designed to be connectable to the skin of the subject and transmit output radiofrequency signals to the organ and sense input radiofrequency signals of the organ (figs. 5A & B; col. 5, lines 45-64 of Ruben). A mixer 42 electrically communicates with the generator and some of the electrodes and mixes the output signals and input signals to provide a mixed radiofrequency signal indicative of the blood flow (see entire document, especially fig. 12; col. 8, line 52-col. 9, line 52; . Electronic circuitry filters out a portion of the mixed signal (col. 7, lines 3-17; col. 7, line 51-col. 8, line 37 of Ruben).

As to the limitation "so as to substantially increase a signal-to-noise ratio of a remaining portion of said mixed radiofrequency signal", applicants should note that this is merely intended use language which cannot be relied upon to define over the prior art of record, since Ruben teaches all of the claimed structural features and their recited

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relationships. Circuitry that filters out an unwanted portion of the signal necessarily eliminates noises, thereby increasing a signal-to-noise ratio.

Regarding claims 79 and 109, the circuitry comprises a digitizer 120, wherein the digitizer is capable of digitizing any radiofrequency signal (col. 7, lines 22-23 of Ruben). Applicants should note that “for digitizing . . .” is merely “intended use” language.

Regarding claims 80 and 110, the electronic circuitry is designed and constructed so as to minimize sensitivity of the input radiofrequency signals to impedance differences between the plurality of electrodes and the organ of the subject (see entire document, especially figs. 5A, 5B, and 11 of Ruben), wherein applicants disclose the use of two input leads as opposed to one as minimizing effects of impedance differences between the electrodes and the body (see instant disclosure, especially p. 26, lines 23-26).

Regarding claim 88, the language in this claim appears to merely describe a method step describing a step of selecting the number of electrodes, wherein such a method limitation fails to further limit the apparatus of claim 11. At best, the language may be considered “product by process” language wherein the claim is evaluated based on the result of such a step rather than the accomplishment of the step itself. In such a case, the end result of such a step and the invention of Ruben are the same.

Regarding claims 89-91, the plurality of electrodes comprises two, three, or four electrodes (figs. 5A, B of Ruben).

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Regarding claims 92 and 93, at least a portion of the electrodes comprises at least one elongated conducting material constructed and designed to wind at least a portion of an external organ of the subject (see entire document, especially figs. 5A, 5B, 11 of Ruben). As to the language "so as to have a substantial constant sensitivity to electrical signals transmitted through said electrodes, irrespective of an orientation of said electrodes on said external organ", the applicants should note that this is merely "intended use" and/or "results" language, which cannot be relied upon to define over the prior art of record, since Ruben, teaches the claimed structural features and their recited relationships. It is submitted that since Ruben teaches electrodes constructed and designed as claimed to wind at least a portion of the organ, then the electrodes must have a "substantial" constant sensitivity as claimed.

Regarding claim 94, at least a portion of the plurality of electrodes comprises an attaching material (see entire document, especially col. 5, lines 57-64 of Ruben).

Regarding claim 95, said external organ is a leg or an arm (see entire document, especially col. 5, lines 47-59 of Ruben).

Regarding claim 96, a bioimpedance detector electrically communicates with at least a portion of the electrodes for detecting a voltage between a first and second location of the subject and for generating the input signals in response to the voltage, wherein the input signals are indicative of impedance (col. 5, line 45-col. 6, line 47 of Ruben).

Regarding claims 101 and 102, the system comprises a display device, wherein a personal computer generally refers to the system built around a microprocessor for

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personal use, including the input/output devices and peripherals that a general user would require, wherein such device include a display. With further regard to claim 102, a general display for a personal computer is certainly capable of displaying the blood flow as a function of time.

Claims 75, 89-97, 101, and 105, are rejected under 35 102(b) as being anticipated by US 6339722 to Heethaar et al. Regarding claims 75 and 105, Heethaar teaches a radiofrequency generator 7 for generating output radiofrequency signals (see entire document, especially the abstract; fig. 1a; col. 5, lines 1-2 of Heethaar). A plurality of electrodes 2-5 are connectable to the skin and transmit output radiofrequency signals and sense input radiofrequency signals of the organ (see entire document, especially fig. 1a; col. 5, lines 1-12 of Heethaar). A mixer 6, 13, 14, 15 electrically communicates with the generator and at least a portion of the electrodes and mixes the input and output signals so as to provide a mixed radiofrequency signal being indicative of the blood flow (see entire document, especially fig. 1a; col. 5, lines 13-29 of Heethaar). Electronic circuitry 47 filters out a portion of the signal so as to substantially increase signal-to-noise ratio of a remaining portion of the mixed signal (see entire document, especially fig. 6; col. 8, lines 54-63 of Heethaar).

Regarding claims 92 and 93, at least a portion of the electrodes comprises at least one elongated conducting material constructed and designed to wind at least a portion of an external organ of the subject (see entire document, especially 1a of Heethaar). As to the language "so as to have a substantial constant sensitivity to

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electrical signals transmitted through said electrodes, irrespectively of an orientation of said electrodes on said external organ", the applicants should note that this is merely "intended use" and/or "results" language, which cannot be relied upon to define over the prior art of record, since Heethaar, teaches the claimed structural features and their recited relationships. It is submitted that since Ruben teaches electrodes constructed and designed as claimed to wind at least a portion of the organ, then the electrodes must have a "substantial" constant sensitivity as claimed.

Regarding claims 89-91, the plurality of electrodes comprises two, three, or four electrodes 4, 5, 10, 11 (see entire document, especially fig. 1a; col. 5, lines 1-12 of Heethaar).

Regarding claim 95, the external organ is the chest, neck, or abdomen (see entire document, especially fig. 1a of Heethaar).

Regarding claim 96, a bioimpedance detector 13, 15 electrically communicates with at least a portion of the electrodes 10, 11 for detecting a voltage between a first and second location of the subject and for generating said input radiofrequency signals in response to the voltage, said input radiofrequency signals being indicative of impedance of the organ (see entire document, especially col. 5, lines 6-28 of Heethaar).

Regarding claim 97, at least one sensor senses the voltage, wherein electrodes and amplifier 10, 11, and 13 constitute a sensor for sensing said voltage and generate signals having a magnitude which is a function of blood flow in the organ (see entire document, especially col. 5, lines 6-12 of Heethaar).

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Regarding claim 101, a display device 18 is included (see entire document, especially fig. 1a; col. 5, lines 43-45; col. 2, lines 62-65 of Heethaar), wherein the display device is capable or “for” displaying any information including blood flow or data indicative of blood flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 75, 81, 105 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Re. 30,101 to Kubicek et al. in view of Ruben. Regarding claims 75 and 105, Kubicek teaches a system for measuring blood flow in an organ of a subject, the system comprising a generator 10 for generating output electrical signals (current; see entire document, especially fig. 3; col. 3, lines 58-69 of Kubicek). A plurality of electrodes A-D connect to the skin of the subject, transmit the signals to the organ and sense input signals of the organ (see entire document, especially fig. 1 of Kubicek). A mixer 42 electrically communicates with the generator and at least a portion of the electrodes for mixing the input and output signals, so as to provide a mixed signal indicative of blood flow (see entire document especially fig. 3; col. 4, lines 1-14 of Kubicek). Kubicek is silent as to the frequency of the output electrical signals

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and further lacks electronic circuitry constructed and designed to filter out a portion of the mixed signal so as to substantially increase a signal-to-noise ratio of a remaining portion of the mixed signal.

However, Ruben teaches delivering an electrical signal to the body for measuring impedance, wherein the signal is a radiofrequency signal (see entire document, especially col. 4, lines 32-40; col. 5, lines 28-30 of Ruben). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the frequency of the signals of Ruben as that of Kubicek, since Kubicek teaches inputting signals to a body for measuring impedance and Ruben describes a frequency of a signal suitable for measuring such impedance. Kubicek, as modified, lacks electronic circuitry constructed and designed to filter out a portion of the mixed signal so as to substantially increase a signal-to-noise ratio of a remaining portion of the mixed signal.

However, Ruben also teaches using electronic circuitry constructed and designed to filter out a portion of the mixed signal so as to substantially increase a signal-to-noise ratio of a remaining portion of the mixed signal (col. 7, lines 3-17; col. 7, line 51-col. 8, line 37 of Ruben). Therefore, it would have been obvious to one of ordinary skill in the art to combine the system of Ruben with that of Kubicek in order to enable more accurate results by filtering out noise.

As to the limitation "so as to substantially increase a signal-to-noise ratio of a remaining portion of said mixed radiofrequency signal", applicants should note that this is merely intended use language which cannot be relied upon to define over the prior art of record, since Ruben teaches all of the claimed structural features and their recited

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relationships. Circuitry that filters out an unwanted portion of the signal necessarily eliminates noises, thereby increasing a signal-to-noise ratio.

Regarding claims 81 and 111, the differential amplifier is characterized by an impedance being substantially larger than said impedance differences between the plurality of electrodes and the organ of the subject (see entire document, especially col. 4, lines 15-26 of Kubicek).

Claims 75 and 105 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4437469 to Djordjevich et al. in view of US Re. 30101 to Kubicek et al. and US 5642734 to Ruben et al. Djordjevich teaches a system for measuring blood flow in an organ of a subject, the system comprising a generator 10 for generating output electrical signals (current; see entire document, especially fig. 3; col. 3, lines 58-69 of Kubicek). A plurality of electrodes A-D connect to the skin of the subject, transmit the signals to the organ and sense input signals of the organ (see entire document, especially fig. 1 of Kubicek). A mixer 42 electrically communicates with the generator and at least a portion of the electrodes for mixing the input and output signals, so as to provide a mixed signal indicative of blood flow (see entire document especially fig. 3; col. 4, lines 1-14 of Kubicek).

Claims 82 and 83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubicek in view of Ruben, as applied to claims 75, 81, 105, and 111 above, and further in view of US 4437469 to Djordjevich et al. Regarding claim 82, Kubicek, as

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modified, discloses determining at least one quantity using the remaining portion of the mixed radiofrequency signal, the quantity being stroke volume or cardiac output (see entire document, especially col. 8, lines 30-45 of Kubicek). Kubicek lacks a processor performing such determination. However, Djordjevich teaches using a data processor to determine stroke volume or cardiac output from impedance values (see entire document, especially fig. 1; col. 6, lines 36-49 of Djordjevich). Therefore, it would have been obvious to one of ordinary skill in the art to use a processor, as shown in Djordjevich, to determine the stroke volume or cardiac output of Kubicek, as modified, in order to make calculations easier for a user, and wherein automating a manual activity fails to distinguish over the prior art (see MPEP 2144.04).

Regarding claim 83, applicants should note that claim 83 fails to recite that the at least one quantity is artery blood flow rate. Kubicek, as modified and described above, teaches the invention of claim 83, where the at least one quantity is stroke volume or cardiac output.

Claim 84 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kubicek in view of Ruben and Djordjevich, as applied to claims 82 and 83 above, and further in view of US 5058583 to Geddes. Kubicek, as modified, lacks a pacemaker to control a heart rate of the subject. However, Geddes teaches a pacemaker communicating with a data processor and operable to control a heart rate of the subject, wherein the data processor is programmed to electronically control the pacemaker in accordance with a stroke volume or cardiac output quantity (see entire document,

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especially col. 8, line 30-col. 9, line 9 of Geddes). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention, in order to automate the delivery of necessary treatment, thereby providing immediate care to a patient.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben, as applied to claims 75, 79, 80, 88-96, 101, 102, 105, 109, and 110, and further in view of US 5817030 to Tarjan et al. Ruben is silent as to whether the electrodes have a substantial constant sensitivity to electrical signals transmitted through the electrodes, irrespective of an orientation of the electrodes on the subject. However, Tarjan teaches electrodes having uniform directionality of response in a plane (see entire document, especially col. 4, lines 4-9 of Tarjan). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the electrodes or electrode arrangement of Tarjan as at least some of the electrodes of Ruben in order to enable easier placement of the electrodes by eliminating the need to place the electrodes according to direction.

Claims 98-100 and 112-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heethaar, as applied to claims 75, 89-97, 101, and 105 above, and further in view of US 3874369 to Asrican. Heethaar lacks a differentiator. However, Asrican teaches an impedance plethysmograph, wherein the electronic circuitry comprises a differentiator for performing at least one time-differentiation, to provide a respective derivative of the impedance between first and second locations (see entire

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document, especially fig. 1; col. 3, lines 8-19 and col. 3, line 60-col. 4, line 5 of Asrican).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the system of Asrican with that of Heethaar in order to determine stroke volume and cardiac output, thereby enabling more comprehensive monitoring of a patient and because Asrican shows that such measurement is desirable.

Regarding claims 99 and 113, the derivative is a first derivative (see entire document, especially col. 3, lines 8-12 of Asrican).

Regarding claims 100 and 114, the differentiator must necessarily be either a digital or an analog differentiator (see entire document, especially fig. 2 of Asrican), as any differentiator must either be a digital or an analog differentiator.

Claims 103, 104, 115, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruben, as applied to claims 75, 79, 80, 88-96, 101, 102, 105, 109, and 110 above, and further in view of US 4537200 to Widrow. Ruben lacks increasing the signal-to-noise ratio by at least 10 or 20 dB. However, Widrow discloses acquiring a bioelectrical signal and filtering it so as to increase the signal-to-noise ration by at least 20 dB (see entire document, especially the abstract; col. 6, lines 21-34 of Widrow).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine Widrow with Ruben in order to reduce noise, thereby acquiring a more accurate signal.

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Claims 103, 104, 115, and 116 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubicek in view of Ruben, as applied to claims 75, 77, 105 and 111 above, and further in view of US 4537200 to Widrow. Kubicek, as modified, lacks increasing the signal-to-noise ratio by at least 10 or 20 dB. However, Widrow discloses acquiring a bioelectrical signal and filtering it so as to increase the signal-to-noise ration by at least 20 dB (see entire document, especially the abstract; col. 6, lines 21-34 of Widrow). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine Widrow with Ruben in order to reduce noise, thereby acquiring a more accurate signal.

Allowable Subject Matter

Claims 76, 77, 106, and 107 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 77 and 107, the primary reason for allowance is the inclusion of the mixer being operable to provide a radiofrequency sum and a radiofrequency difference, in combination with all of the other limitations of the claims, which is not taught or suggested by the prior art of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735